

oxide, phenothiazine-5-dioxide, thiathrene-5-dioxide, thiathrene-5-oxide, carbazole, dibenzo[b,d]furan, dibenzo[b,d]thiophene.

## **REMARKS AND ISSUES TO BE RESOLVED**

### **I. The IDS.**

As pointed out in the response to the previous Office Action, copies of the 94 references cited in the Information Disclosure Statement were sent and received by the Patent Office as evidenced by the date-stamped postcard that was forwarded in the previous response. The Applicant's are two individual inventors working at a small Australian university and the cost of recopying and resending the references represents a considerable expense which they have already incurred and the cause of which was not of their doing. While the Applicant's realize that you have not been able to review these references and they will most likely have to be resent, the Applicant's would appreciate if you were sensitive to their situation in this and the matters that follow.

### **II. The Patent Office's rejection of claims 2, 4, 20-31 under 35 U.S.C. §112.**

Claims 2, 4, and 20-31 were rejected for improper Markush language. These claims will be amended to recite proper Markush claim language in accordance with your suggestion.

### **III. The Patent Office's rejection of claim 6 under 35 U.S.C. §112.**

Claim 6 was rejected for reciting "5 R<sub>1</sub> groups". R<sub>1</sub> is defined in lines 21-25 of claim 6 and therefore this term appears to be definite.

### **IV. The Patent Offices's objection to the term "biological modulator" under 35 U.S.C. §112.**

While the Applicant's realize that you would like this term to be amended to recite terms which reflects either increasing or decreasing the biological activity of insulin,

the Applicant's believe that this will double the number of claims and narrow the intended scope of the invention without conveying additional clarity. The plain meaning of the term modulator, the noun form of the verb modulate, means "to adjust" or "vary." Merriam-Webster's Collegiate Dictionary, 10<sup>th</sup> Edition, p. 748, col. 1. This term conveys that such variation may involve either decreasing or increasing that which is being adjusted. This is the reason this term was used in the specification and the claims, because the term "modulator" is commonly used in the art to encompass these opposing activities. For example see issued U.S. Patent No. 6,413,735 (using the term "modulator" to refer to both an inhibitor (decreasing activity) and a promoter (increasing activity) in its claims.) The term "biological modulator" is used in the specification and the claims because the compounds of the invention "may act either as agonists or antagonists" of insulin or insulin-like activity. (see page 14 lines 22-23).

#### **IV. The Patent Offices's objection to the term "insulin related ailment" under 35 U.S.C. §112.**

Likewise, the term "related ailments" is also commonly used in the art in the context of referring to ailments which are related to the presence of a particular system, indication, or compound. For example see issued U.S. Patent Nos. 6,453,204 and 5,995,873 (claiming a "method of treating a human for ailments related to the nervous system"); 5,020,520 (claiming a "therapeutic device for treating a patient's pain and other related ailments"); 4,536,495 (claiming a "method for the treatment of ailments related to the bladder function in man"); 4,411,904, 4,364,954, and 4,292,321 (claiming a "pharmaceutical composition for treating schizophrenia and related ailments in mammals"); 4,278,676 (claiming a "method for treating GABA system malfunction-related diseases in living animals"); and 3,961,060 (claiming a "method for alleviating depression and ailments which are related to a decreased activity of the dopamine system in the brain").

#### **V. The Patent Offices's objection to the term "associated " under 35 U.S.C. §112.**

Finally, the term "associated" is commonly used in the art in the context of referring to a region of a compound that is responsible for binding to its receptor is commonly used in the art to encompass these opposing activities. See issued U.S. Patent No. 6,495,314 (claiming the step of "detecting and identifying each of the peptide cleavage

products . . . . for identifying amino acids within the amino acid sequence of the protein  
*associated with binding to the target molecule.*" ) (Emphasis added).

Applicants believe that the claims are imbued with clarity and these 35 U.S.C.  
§ 112, second paragraph rejections should be withdrawn. In the event that the Examiner  
maintains these rejections, Applicants would welcome discussions with the Examiner  
regarding alternative acceptable terms that are synonymous with this term that are equally  
defined by the disclosure. I look forward to discussing the above issues with you on  
Tuesday, February 18, 2003 2:00 p.m. EST. in order to place the application in condition for  
allowance.

Respectfully Submitted,

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